2. Summary & Certification

2.1 Summary of safety and effectiveness information

2.1.1 General Information

Device Generic Name: Endocardial pacing lead.

Device Trade Name: Stela™ Model BT45/46, UT46, BJ44/45 and UJ45 Pacing Leads

Applicant's Name and Address: ELA Medical, Inc., 2950 Xenium Lane North, Plymouth, MN 55441, Tel. (612) 519-9400

Date of Summary Preparation:

Contact Person: Catherine G. Goble

510(k) Number: K

Date of Judgment of Substantial Equivalence Sent to Applicant:

Predicate Devices:

Device	**510(k) Number**
ELA Medical Stela™ Model BT45/46 and UT46	K904255
ELA Medical Stela™ Model BJ44/BJ45	K963698
ELA Medical Stela™ Model UJ45	K972574

2.1.2 Description of Conditions for Which the Devices are Indicated

The Stela™ Model BT45/46, UT46, BJ44/45 and UJ45 pacing leads are indicated for cardiac pacing and sensing, which is the same as other transvenous pacing leads.

2.1.3 Device Description

Stela™ Model BT45/46 and UT46 straight tined pacing leads are silicone rubber, transvenous leads that provide a permanent electrical pathway between a pacemaker and the ventricle.

Stela™ Model BJ44/45 and UJ45 J-shaped pacing leads are silicone rubber, transvenous leads that provide a permanent electrical pathway between a pacemaker and the atrium.

Stela™ Model UT 46 and UJ45 are silicone rubber, unipolar transvenous leads, similar in design and construction to bipolar models BT45/46 and BJ44/45, respectively.

The following silicone rubber material change was performed on Stela™ Model BT45/46, UT46, BJ44/45 and UJ45 pacing leads:

Affected components	Current material	New material
Molded parts (connector and distal-assembly moldings and anchoring sleeve)	Dow Corning Q7-4750, Q7-4765 and Q7-4780	Rhodia Silicones* LSR (liquid silicone rubber), part number 40028

* Rhodia Silicones (formerly Applied Silicone Corporation), 320 West Stanley Avenue, Ventura CA 93001

2.1.4 Alternatives

The alternatives for Stela™ Model BT45/46, UT46, BJ44/45 and UJ45 leads are other commercially available transvenous pacing leads.

2.1.5 Marketing History

Commercial distribution of the modified Stela™ Model BT45/46, UT46, BJ44/45 and UJ45 leads has not started anywhere yet.

2.1.6 Potential Adverse Effects

The potential adverse effects of Stela™ Model BT45/46, UT46, BJ44/45 and UJ45 pacing leads are the same as those for other implantable endocardial leads in commercial distribution. Lead-related complications are described in the ELA Medical generic lead manual.

2.1.7 Summary of Studies

The following in-vitro functional testing was performed on the modified Stela™ Model BT45/46, UT46, BJ44/45 and UJ45 pacing leads: electrical isolation, connector insertion/extraction, leak resistance, connector hermeticity, tensile strength.

In addition to raw material biocompatibility test results provided in Applied Silicone Corporation's Master file, the following biocompatibility tests were performed on products manufactured by ELA Medical using raw materials from Applied Silicone Corporation (now called Rhodia Silicones):

- Implantation, according to ISO 10993-6: tissue analysis after 3- and 6-month endocardial implantation in sheep (4 animals at 3 months, 4 animals at 6 months).
- Histology, according to ISO 10993-6.
- Blood-compatibility, according to ISO 10993-4: hemolysis test, coagulation time.

Note that the 3-month implantation, histology and blood-compatibility test reports were already submitted as part of 510(k) K993448.

2.1.8 Conclusion

The information presented in this submission provides reasonable assurance that the modified Stela™ Model BT45/46, UT46, BJ44/45 and UJ45 pacing leads will perform in a safe and effective manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2000

Ms. Catherine G. Goble
Regulatory Affairs Manager
ELA Medical, Inc.
2950 Xenium Lane North
Plymouth, MN 55441

Re: K000029
Stela™ Models UT46, BT45/46, UJ45, and BJ44/45 Endocardial Pacing Leads
Regulatory Class: III (Three)
Product Code: DTB
Dated: January 4, 2000
Received: January 5, 2000

Dear Ms. Globe :

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notifications. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.10 Indications for Use Statement

510 (k) Number: K

Device Name: Stela™ Model BT45/46, UT46, BJ44/45 and UJ45 Pacing Leads.

Indication for Use:

ELA Medical endocardial leads are designed to be used with implantable cardiac pacemakers.

ELA Medical Stela™ Model BT45/46 and UT46 straight tined pacing leads are intended for implantation in the ventricle.

ELA Medical Stela™ Model BJ44/45 and UJ45 J-shaped pacing leads are intended for implantation in the atrium.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

for Dillard.

(Division Sign-Off)

Division of Cardiovascular, Respiratory,

and Neurological Devices

510(k) Number K000029